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(54) Bifurcated stent assembly

Bifurkations-Stent Fabrikat

Dispositif de stent avec bifurcation

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(73) Proprietor: **Boston Scientific Technology Inc.**
Maple Grove, MN 55311-1566 (US)

(72) Inventors:
- **Goicoechea, George**
  Freeport (BS)
- **Hudson, John**
  Clearwater, Florida 34619 (US)
- **Mialhe, Claude**
  83300 Draguignan (FR)
- **Cragg, Andrew Harold**
  Edina MN 55424 (US)
- **Dake, Michael David**
  Stanford CA 94305 (US)

(74) Representative:
Crump, Julian Richard John et al
FJ Cleveland,
40-43 Chancery Lane
London WC2A 1JQ (GB)

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Description

[0001] The present invention relates to a bifurcated endoluminal prosthesis for use in a bifurcated blood vessel such, for example, as the infrarenal portion of a mammalian aortic artery where it bifurcates to the common iliac arteries.

[0002] A stent is used to provide a prosthetic intraluminal wall e.g. in the case of a stenosis to provide an unobstructed conduit for blood in the area of the stenosis. An endoluminal prosthesis comprises a stent which carries a prosthetic graft layer of fabric and is used e.g. to treat an aneurysm by removing the pressure on a weakened part of an artery so as to reduce the risk of embolism, or of the natural artery wall bursting. Typically, a stent or endoluminal prosthesis is implanted in a blood vessel at the site of a stenosis or aneurysm by so-called "minimally invasive techniques" in which the stent is compressed radially inwards and is delivered by a catheter to the site where it is required through the patient's skin or by a "cut down" technique in which the blood vessel concerned is exposed by minor surgical means. When the stent is positioned at the correct location, the catheter is withdrawn and the stent is caused or allowed to re-expand to a predetermined diameter in the vessel.

[0003] US-A-4 994 071 specifies a prosthesis for use at an angeological bifurcation of a blood vessel into two branched vessels, characterised by:

a first prosthesis member including a stent and adapted to be retained in said blood vessel, said first prosthesis member being bifurcated and including a proximal portion adapted to be positioned in service in juxtaposition with the angeological bifurcation, and two distal portions adapted to extend across the angeological bifurcation and into each of the branched vessels.

[0004] FR-A-2 678 508 specifies a prosthesis for use at an angeological bifurcation of a blood vessel into two branched vessels, characterised by:

a first prosthesis member including a stent and adapted to be retained in said blood vessel, said first prosthesis member including a proximal portion adapted to be positioned in service in juxtaposition with the angeological bifurcation, and one distal portion and a second prosthesis member also including a stent and adapted to be joined in situ with said one distal portion of said first prosthesis member, said second prosthesis member being adapted to extend across the angeological bifurcation and into one of the branched vessels.

[0005] U.S. Patent 4,886,062 discloses a vascular stent which comprises a length of sinuous or "zig-zag" wire formed into a helix; the helix defines a generally cylindrical wall which, in use, constitutes a prosthetic intraluminal wall. The sinuous configuration of the wire permits radial expansion and compression of the stent; US-A-4886062 discloses that the stent can be delivered percutaneously and expanded in situ using a balloon catheter.

[0006] U.S. Patent 4,733,665 discloses an expandable intraluminal graft which is constituted by a tubular member formed from a plurality of intersecting elongate members which permit radial expansion and compression of the stent.

[0007] EP-A-0556850 discloses an intraluminal stent which is constituted by a sinuous wire formed into a helix; juxtaposed apices of the wire are secured to one another so that each hoop'of the helix is supported by its neighboring hoops to increase the overall strength of the stent and to minimize the risk of plaque hemiation; in some embodiments the stent of EP-A-0556850 further comprises a tubular graft member to form an endoluminal prosthesis.

[0008] The prior art stents and prostheses mentioned above are generally satisfactory for the treatment of aneurysms, stenoses and other angeological diseases at sites in continuous unbifurcated portions of arteries or veins.

[0009] However, the prior art stents and prostheses are not wholly satisfactory for use where the site of desired application of the stent or prosthesis is juxtaposed or extends across a bifurcation in an artery or vein such, for example, as the bifurcation in the mammalian aortic artery into the common iliac arteries. For example, in the case of an abdominal aortic aneurysm ("AAA") in the infrarenal portion of the aorta which extends into one of the common iliac arteries, the use of one of the prior art prosthesis referred to above across the bifurcation into the one iliac artery will result in obstruction of the proximal end of the other common iliac artery; by-pass surgery is therefore required to connect the one iliac artery in juxtaposition with the distal end of the prosthesis to the other blocked iliac artery. It will be appreciated by a person skilled in the art that it is desirable to avoid surgery wherever possible; the requirement for by-pass surgery associated with the use of the prior art prosthesis in juxtaposition with a bifurcation in an artery therefore constitutes a significant disadvantage.

[0010] According to the present invention there is provided a prosthesis as claimed in claim 1 below.

[0011] Throughout this specification, the term "proximal" shall mean "nearest to the heart," and the term "distal" shall mean "furthest from the heart."

[0012] Typically, the proximal end of said bifurcated member may be flared radially outwardly towards its extremity to engage the endoluminal surface of the artery thereby to resist longitudinal movement of the bifurcated member in service.

[0013] The male engaging portion of the second prosthesis member may be flared radially outwardly towards its extremity, and the female cooperating portion of the first prosthesis member may be tapered radially inwardly towards its extremity. In some embodiments, the male engaging portion may comprise a frustoconical wall which flares outwardly towards its longitudinal extremity; the female cooperating portion may comprise a frustoconical wall which tapers radially inwardly towards its

longitudinal extremity.

[0014] Alternatively, said male engaging and female cooperating portions may be substantially untapered; they may be substantially cylindrical.

[0015] The male engaging portion of the second prosthesis member may be resiliently compressible in a radially inwards direction such that in the radially compressed state it is capable of self-re-expansion to engage in the female cooperating portion. Typically, each of said first and second prosthesis members may be resiliently compressible.

[0016] In use therefore the first prosthesis member may be delivered in a radially compressed state by using a catheter; when the first prosthesis member is located at the site of use, the catheter may be withdrawn thereby allowing the first prosthesis member to re-expand to engage the endoluminal surface of the blood vessel.

[0017] The second prosthesis member may then be delivered percutaneously or by a "cut down" technique to a site distal of the first prosthesis member such that the male engaging portion of the second prosthesis member in the radially compressed state is entered into the expanded female cooperating portion of the first prosthesis member; the catheter may then be withdrawn allowing the second prosthesis member to re-expand such that the male engaging portion engages in the female cooperating portion of the first prosthesis member.

[0018] In some embodiments of the present invention each of the distal portions of the first prosthesis member may comprise a distal female cooperating portion adapted to engage a male engaging portion of another prosthesis member.

[0019] One of the distal portions of said first prosthesis member may extend across the bifurcation into a respective one of the branched blood vessels.

[0020] One of the distal portions may be adapted to be joined to the second prosthesis member, and the other distal portion may be adapted to extend across the angeological bifurcation to allow blood flow into the other of the branched vessels.

[0021] Each of the prosthesis members may comprise a stent comprising a sinuous wire formed into a tubular configuration. The sinuous and tubular configurations may be imparted to the wire by winding it on a mandrel. Typically, each stent may be made from a shape memory nitinol (nickel~titanium) wire which may be wound on to the mandrel to form the stent in a tubular configuration of slightly greater diameter than the diameter of the blood vessel in which the stent is intended to be used. The stent may be annealed at an elevated temperature and then allowed to cool in air so that the nitinol wire "remembers" the configuration in which it was wound on the mandrel.

[0022] Said nitinol wire may be type "M" nitinol wire which is martensitic at temperatures below about 13°C and is austenitic at temperatures above about 25°C; it will be appreciated therefore that the type "M" wire will be austenitic at body temperature of 37°C. Typically, the annealing may be conducted at about 500°C or more for at least about 60 minutes; after cooling the wire may be immersed in cold water to facilitate removal of the wire from the mandrel with the wire in its maleable martensitic form. Typically, the cold water may have temperature of less than about 10°C; the wire may be immersed for about 5 minutes or more. An advantage of using nitinol wire to form the stent in accordance with the present invention is that the nitinol wire is "super elastic" in its austenitic state; the radial outward force exerted by the stent on the wall of the blood vessel in use is therefore substantially constant irrespective of the diameter of the vessel and the expanded stent.

[0023] In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent. Each hoop may comprise a substantially complete turn of the wire having a sinuous configuration; optionally, as each hoop is completed, the point of winding the wire may be displaced longitudinally with respect to the winding axis to form the next hoop. When the next hoop is complete, the point of winding is moved further longitudinally with respect to the winding axis to the form the next succeeding hoop and so on.

[0024] It will appreciated that an advantage of this novel arrangement is that the planes of the hoops are not skewed with respect to the longitudinal axis of the stent; the longitudinal ends of the stent are "square" to said longitudinal axis, so that when the stent is caused or allowed to expand in situ there is substantially no twisting of the stent as it shortens in length. It will be appreciated that this represents a significant advantage, as in areas of stenosis or aneurysm it is desirable to minimize the movement of the stent within the blood vessel so as to reduce the potential trauma to the patient.

[0025] Typically, the stents whether of the helical or perpendicular variety, also comprise securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. The securing means may comprise a loop element of a suture material, for example, to tie the juxtaposed apices together; the loop element may also comprise a loop formed of a thermoplastics material such, for example, as polypropylene, alternatively, the securing means may be a bead formed of a thermoplastic material around juxtaposed apices. Also alternatively, the securing means may be a loop, ring, or staple formed of wire such as nitinol.

[0026] The male engaging portion and female cooperating portion, of the interengaging prosthesis members of this invention, may be formed separately from the remainder of the respective non-engaging portions of these prostheses and then the engaging and non-engaging portions secured to one another by securing

means.

[0027] In one embodiment of the present invention, proximal and distal prosthesis portions of the bifurcated prosthesis member in accordance with the present invention may be formed separately. The distal end of the proximal prosthesis portion may be secured to the wider proximal end of a first intermediate frustoconical prosthesis portion; the narrower distal end of the first intermediate frustoconical prosthesis portion may be secured to the proximal end of a distal prosthesis portion. The female cooperating portion of the bifurcated prosthesis may be constituted by a second frustoconical prosthesis portion which is secured to the distal end of the proximal prosthesis portion in juxtaposition with the first frustoconical portion.

[0028] Alternatively the first and second frustoconical portions may be omitted; the proximal and distal prosthesis portions may be secured directly one to the other.

[0029] The female cooperating portion may be constituted by a generally cylindrical prosthesis portion secured to said proximal prosthesis portion in transversely spaced relation to the other distal portion.

[0030] Each of the first and second prosthesis members of the prosthesis of the present invention may carry a tubular graft layer formed from a biocompatible fabric in juxtaposition with a stent. Typically the graft layer may be disposed externally of the stent; it will be appreciated however that in some embodiments the graft layer may be disposed internally of the stent. In some embodiments the graft layer may be secured to the stent by loop elements such, for example, as loops of polypropylene. The biocompatible fabric may be a polyester fabric or a polytetrafluoroethylene fabric; typically said fabric may be woven or a warp knitted polyester fabric. In some embodiments the woven or a warp knitted fabric may be formed in a seam-free bifurcated configuration as a sleeve for a bifurcated stent.

[0031] In some embodiments the male engaging portion of the second prosthesis member and the female cooperating portion of the first prosthesis member may be left uncovered. Alternatively, the fabric graft layer may extend to the proximal extremity on the external surface of the male engaging portion, and may be folded over the distal extremity of the female engaging portion to form an inner sleeve: in use the external fabric of the male engaging portion may butt against the folded over portion of the fabric internally of the female cooperating portion to form a substantially blood tight seal.

[0032] The second prosthesis member having the male engaging portion may also have a tubular graft layer. If required, the second prosthesis member may be introduced in a radially compressed state such that the male engaging portion of the second prosthesis member is engaged in the intermediate female cooperating portion of the bifurcated prosthesis member; the second prosthesis member is then caused to be allowed to re-expand in situ such that the male engaging portion engages in the female cooperating portion to resist longitudinal separation of the two prosthesis members in service.

[0033] The bifurcated prosthesis member may be adapted for use in the infrarenal portion of a mammalian aorta in juxtaposition with the bifurcation of the common iliac arteries for the treatment of abdominal aortic aneurysms. In use the bifurcated endoluminal prosthesis member may be introduced into the infrarenal portion of the aorta using a catheter such that the at least one distal prosthesis portion extends into one of the branched iliac arteries: the catheter may then be withdrawn allowing the prosthesis member to re-expand in situ.

[0034] It will be appreciated by a person skilled in the art that the prosthesis member may be introduced to the site of use percutaneously or by "cut down" techniques.

[0035] The prosthesis according to this invention may be provided on its external surface with circumferentially spaced wire barbs or hooks adapted to engage in the endoluminal surface of the host artery to resist longitudinal movement or slippage of the stent in use. Typically the barbs or hooks may be disposed on part of a stent which is provided with a fabric graft layer such that in use the points of the artery which are engaged by the barbs or hooks are covered by the fabric graft. It will be appreciated by a person skilled in the art that the trauma to the artery wall caused by the hooks or barbs may cause emboli; the provision of a fabric graft over the barbs or hooks in use will therefore help to prevent the introduction of such emboli into the blood stream.

[0036] Alternatively, the barbs may be sewn onto the outside surface of the fabric.

[0037] The male engaging portion for the second prosthesis member may be provided with circumferentially spaced hooks or barbs on its external surface to engage the internal surface of said female cooperating means, thereby to reinforce the connecting means against longitudinal separation of the prosthesis member one from the other in the service.

[0038] It will be appreciated that the present invention represents a significant step forward in the art as it allows the provision of a bifurcated endoluminal prosthesis for use in juxtaposition e.g. with arterial bifurcations without requiring by-pass surgery to connect one of the branched arteries to the other branched artery.

[0039] In particular, a bifurcated endoluminal prosthesis member of the invention can be positioned in an artery in juxtaposition with a bifurcation to extend into one of the branched arteries; the bifurcated prosthesis member can be connected to another prosthesis member which extends in the other branched artery. The prosthesis member can be delivered percutaneously or by "cut down" methods and connected together in situ thereby to provide effective treatment of an angeological disease such, for example, as an aneurysm or a stenosis which extends across a bifurcation in a blood vessel without the need for by-pass surgery.

[0040] Following is a description by way of example only with reference to the accompanying drawings of

embodiments of the present invention.

In the drawings: -

[0041] Figure 1a is a front view of a bifurcated intraluminal stent constituting part of an endoluminal prosthesis in accordance with the present invention.

[0042] Figure 1b is a front view of another stent which is adapted to be connected to the bifurcated stent of Figure 1a.

[0043] Figure 2(a) is a side view of part of the bifurcated stent of Figure 1a opened up to show its construction.

[0044] Figure 2(b) is a side view of an exemplary mandrel used to form the part of the bifurcated stent shown in Figure 2(a).

[0045] Figure 3 is a side view of another part of the bifurcated stent of Figure Ia opened up to show its construction.

[0046] Figure 4(a) is a side view of yet another part of the bifurcated stent of Figure 1a opened up to show its construction.

[0047] Figures 4(b)-4(f) are partial exploded views of the exemplary stent of Figure 4(a) illustrating alternative means for securing juxtaposed apices according to the present invention.

[0048] Figure 5 is a schematic perspective view of a bifurcated endoluminal prosthesis in accordance with the present invention.

[0049] Figure 6 is a schematic view of another bifurcated endoluminal prosthesis in accordance with the present invention.

[0050] Figure 7 is a schematic view of yet another bifurcated endoluminal prosthesis in accordance with the present invention.

[0051] Figures 8 and 9 are side views of alternative prosthesis members.

[0052] The present invention includes apparatus for treating angeological diseases in any bifurcated blood vessel. One example of such a bifurcated blood vessel is the infrarenal portion of a mammalian aortic artery where it bifurcates to the common iliac arteries. Examples of diseases that can be treated using the apparatus and method of the present invention include aneurysm, stenosis, and occlusion.

[0053] A bifurcated stent which is indicated at 10 in Figure 1a comprises a wire skeleton which is constructed in four separate parts, namely a proximal part 12, a first frustoconical part 14, a first distal part 16 and a second frustoconical part 18. Said bifurcated stent 10 carries a fabric graft layer (Figures 5, 6, and 7) for use as an endoluminal prosthesis e.g. in the infrarenal portion of a mammalian aorta in juxtaposition with the bifurcation of the common iliac arteries. It will be appreciated, however, that bifurcated stents for use in different parts of the angeological system and for different mammals can be constructed in accordance with the invention by varying the dimensions of the stent accordingly.

[0054] Each of the four parts of the bifurcated stent 10 is made in substantially the same way by winding a shape memory nitinol wire, typically nitinol type M wire, onto a mandrel 46.

[0055] The construction of the exemplary proximal part 12 of the bifurcated stent 10 is shown in Figures 2 (a) and 2(b); nitinol wire type M wire typically having a diameter of 0.46mm (0.018") is wound around mandrel 46 to form a plurality of hoops 20. The winding surface of mandrel 46 is provided with a plurality of upstanding pins 47 disposed in a zig-zag pattern for each of the hoops 20 so that in each hoop 20 the nitinol wire follows a sinuous path to define a plurality of circumferentially spaced apices 22. Each hoop 20 is wound onto mandrel 46 such that the plane of the circumference of each hoop 20 is substantially perpendicular to the longitudinal axis of the mandrel.

[0056] When one hoop 20 e.g. the hoop indicated at 20a has been formed, the point of winding of the nitinol wire is displaced longitudinally with respect to the axis of mandrel 46 to form the next successive hoop 20b. The stent shown in Figure 2(a) is the stent formed on mandrel 46 shown in Figure 2(b) after cutting the stent longitudinally and rotating it 45 degrees to show the construction of the stent.

[0057] The proximal part of the exemplary bifurcated stent of Figure 1a is formed on the mandrel with a diameter of about 24mm and a length in the longitudinal direction of about 55mm. From Figures 1(a), 2(a), and 2 (b) it will be noted that the proximal part 12 is constituted by three hoops 20 of unit width at the proximal end 24 of the proximal part 12, two intermediate hoops 25 of twice unit width and, at its distal end 26, by a single hoop 20 of unit width. In the illustrated embodiment, intermediate hoops 25 have a plurality of offsets 25a. Offsets 25a are formed when the wire is passed around pins 47 on mandrel 46. Offsets 25a add stability to the stent. When the nitinol wire has been wound onto mandrel 46, the nitinol wire is annealed at an elevated temperature and then allowed to cool.

[0058] In this embodiment of the invention the wire is annealed at a temperature of about 500°C for 60 minutes and is then allowed to cool in air. The purpose of the annealing is so that the nitinol wire in its austenitic form "remembers" its configuration as wound on mandrel 46; it will be appreciated therefore that other temperatures and durations for the annealing are included within the present invention provided the nitinol wire "remembers" its wound configuration.

[0059] After annealing and cooling, the wire is immersed in cold water at less than 10°C for about 5 minutes; the wire is then removed from the mandrel, and juxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 (see Figure 4(a)), which are, in this example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which has a juxtaposed apex of a neighboring hoop 20 is tied to the juxtaposed apex 22. It will be appreciated, however, that in other embodiments of the invention only some of the juxtaposed apices 22 may be secured in this way.

[0060] In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in Figure 4(b). The securing means may also comprise bead 99b formed of a thermoplastic material around juxtaposed apices, as shown in Figure 4(c). Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in Figures 4(d), 4(e), and 4(f) respectively.

[0061] The exemplary first and second frustoconical parts 14, 18 of the skeleton shown in the figures are formed in substantially the same way as the proximal part 12 by winding nitinol wire onto a mandrel and then annealing the wire before removing it from the mandrel. As shown in Figure 3, the first and second frustoconical parts 14, 18 are each constituted by three hoops 20 of unit width. The mandrel is tapered such that the proximal end of each of the exemplary frustoconical parts 14, 18 is formed with a diameter of about 12mm and the distal end 32 of each is formed with a diameter of about 9mm. The overall length of each of the exemplary frustoconical parts 14, 18 is about 18mm. The wire used for the frustoconical parts 14, 18 is nitinol type M wire having a diameter of 0.28mm (0.011"). Juxtaposed apices 22 of each of the exemplary frustoconical parts 14, 18 are tied together using 0.03" polypropylene filaments as described above. The first and second frustoconical parts 14, 18 are secured to the distal end 26 of the proximal part 12 of the stent 10 in transversely spaced relation as shown in Figure 1a by securing the apices 22 of the hoop 20 forming the wider proximal end 30 of each of the frustoconical parts 14, 18 to juxtaposed apices 22 of the hoop 20 on the distal end 26 of the proximal part 12.

[0062] The exemplary first distal part 16 of the bifurcated stent 10 is formed by winding nitinol type M wire typically having a diameter of 0.28mm (0.011") onto a mandrel to form twelve longitudinally spaced hoops 20 as shown in Figure 4; the exemplary first distal part has an overall length of about 66mm and a uniform diameter of about 9mm. The proximal end 34 of the distal part 16 is secured to the narrower distal end 32 of the first frustoconical part 14 by tying each apex 22 on the proximal end 34 of the first distal part 16 to a juxtaposed apex on the distal end 32 of the first frustoconical part 14 using, in this embodiment, 0.003" polypropylene filaments.

[0063] The proximal part 12, the first and second frustoconical parts 14, 18, and the first distal part 16 are each covered with a tubular graft layer of a biocompatible woven fabric (Figures 5, 6, and 7) such, for example, as a plain woven fabric made from 30 or 40 denier polyester. The tubular fabric layers may be attached to the proximal and distal parts 12, 16 of the stent 10 by stitching with, for example, 0.003" polypropylene filaments around the apices 22 of the underlying skeleton. The fabric covered stent constitutes one form of an endoluminal prosthesis.

[0064] The proximal part 12 of the wire skeleton may be provided with a plurality of circumferentially spaced hooks or barbs 43 which project through the tubular fabric layer to engage in the endoluminal surface of a host artery in service.

[0065] The sinuous configuration of each turn 20 of the wire skeleton of the stent 10 allows the prosthesis to be compressed resiliently radially inwards so that it can be received in a catheter e.g. a 16 or 18 French catheter for percutaneous or cut down delivery, e.g. to an intraluminal site in the infrarenal section of the aortic artery. Larger diameter catheters up to, e.g., 20 French, may be used to deliver the prosthesis using "cut down" procedures.

[0066] An x-ray opaque marker may be attached to one or more ends of a stent so that the delivery of the stent can be monitored using x-rays. As shown in Figure 4(a), such a radiopaque marker may typically comprise a gold or platinum wire 17 crimped onto an end of stent 16. Alternatively, the radiopaque marker may be a tube 17a disposed around a length of wire on the stent, also as shown in Figure 4(a). Typically, in the bifurcated stent the marker is secured to the stent in line with the distal stent portion so that the distal stent portion can be aligned with and inserted into one of the branched arteries in situ.

[0067] The bifurcated endoprosthesis is positioned in the infrarenal section of the aortic artery in juxtaposition with the bifurcation of the common iliac arteries such that the first distal part 16 of the prosthesis extends into one of the common iliac arteries. The catheter is then withdrawn allowing the stent 10 to re-expand towards its configuration as wound on the mandrel in which it was annealed until the stent engages the endoluminal surface of the host artery. The barbs or hooks engage the endoluminal surface of the host artery to resist longitudinal displacement or slipping of the prosthesis in use.

[0068] It will be appreciated that when the bifurcated prosthesis is positioned and re-expanded in the fitted position, blood can flow from the aortic artery into the proximal part 12 of the prosthesis from where it can flow into the one common iliac artery through the frustoconical part 14 and the first distal part 16 and also into the other common iliac artery through the second frustoconical part 18.

[0069] In cases where it is required to implant a prosthesis in the other common iliac artery a second prosthesis comprising a second stent 40 as shown in Figure 1b can be used. The second stent 40 includes a wire skeleton comprising a proximal frustoconical part 42 and a distal part 44. The distal part 44 of the second stent 40 also may be covered with a tubular graft layer of a biocompatible fabric such, for example, as polyester or polytetrafluoroethylene fabric (Figures 5, 6, and 7).

[0070] The frustoconical proximal part 42 is constructed in the same way as the frustoconical parts 14, 18 of the bifurcated stent 10; the distal part 44 is constructed

in the same way as the distal part 16 of the bifurcated stent 10. The distal end of the frustoconical proximal part 42 is secured to the proximal end of the distal part 44 by securing juxtaposed apices using polypropylene filaments as described above.

[0071] In use, the second prosthesis is compressed radially inwards and is received in a catheter for percutaneous or "cut down" delivery to the other common iliac artery. The frustoconical proximal part 42 is guided, in the radially compressed state, into the second frustoconical part 18 of the bifurcated stent 10. The catheter is then withdrawn allowing the second stent 40 to re-expand towards its remembered configuration, until the distal part 14 engages the endoluminal surface of the other common iliac artery, and the outer surface of the frustoconical proximal part 42 engages the interior surface of the second frustoconical part 18 of the bifurcated stent 10.

[0072] As with other stents described herein, the frustoconical proximal part 42 may be formed with circumferentially spaced barbs or hooks 43, as shown in Figure 1b, which engage in the wire skeleton of the second frustoconical part 18 of the bifurcated stent 10. When barbs 43 are on proximal portion 12, they engage the inner wall of the artery.

[0073] The tapered configurations of the second frustoconical part 18 of the bifurcated stent 10 and of the proximal frustoconical part 42 of the second stent 40 are such that in the fitted position as described, the prosthesis are locked together to resist longitudinal separation in service. Barbs or hooks on the second stent 40 and/or an frustoconical proximal part 42 help to resist such longitudinal separation.

[0074] In another example of the present invention a bifurcated endoluminal prosthesis 50 as shown in Figure 5 includes a bifurcated stent comprising a proximal portion 52 which tapers radially inwardly from its proximal end 54 to its distal end 56, and first and second transversely spaced frustoconical distal portions 58, 60 which are secured to the distal end 56 of the proximal portion 52; the proximal portion 52 is covered with a tubular graft layer of a biocompatible fabric 62.

[0075] In use the prosthesis is delivered percutaneously or by "cut down" methods to an artery in juxtaposition with an arterial bifurcation; blood can flow through the frustoconical proximal portion 52 into each of the branched arteries through the first and second distal frustoconical portions 58, 60. Where a prosthesis is required in one or both of the branched arteries, a separate prosthesis comprising a stent of the type shown in Figure 1b referred to above covered with fabric can be connected to the bifurcated prosthesis 50 by inserting and re-expanding the proximal end of such a separate prosthesis in one or both of the distal frustoconical portions 58, 60 of the prosthesis 50 for engagement therein.

[0076] Another variant of the present invention is shown in Figure 6 which shows a bifurcated endoluminal prosthesis 70 having a proximal portion 72 which is secured at its distal end 74 to two transversely spaced frustoconical intermediate portions 76, 78.

[0077] One of said frustoconical intermediate portions 76 is secured at its distal end to an elongate distal portion 80. The proximal end 82 of the proximal portion 72 is flared radially outwards towards its proximal end 82 to engage the intraluminal surface of the host blood vessel in service. Save for this flared portion, the entire endoprosthesis is covered with a fabric graft layer as shown in Figure 6; said graft layer is carried externally of the wire skeleton and is folded over the distal extremity 84 of the other frustoconical intermediate portion 78 to form an internal lining in said other frustoconical immediate portion 78.

[0078] Said other frustoconical intermediate portion 78 constitutes a female cooperating portion in accordance with the present invention which is adapted to receive a male engaging portion of another prosthesis as indicated at 86 in Figure 6. Said other prosthesis 86 includes a frustoconical proximal portion 88 which constitutes the male engaging portion and an elongate distal portion 90. The whole of the other prosthesis 86 is covered with a fabric graft layer as shown in Figure 6. In service, the male engaging portion 88 of the other prosthesis 86 is entered into and engaged with the female cooperating portion 78 of the bifurcated prosthesis 70 in situ in the manner herein before described. The fabric layer on the male engaging portion 88 butts face-to-face on the folded over portion of the fabric layer disposed internally of the female cooperating portion 78 to form a substantially blood-tight seal therewith.

[0079] Yet another example of the present invention is shown in Figure 7 in which a bifurcated endoluminal prosthesis 91 has a generally cylindrical proximal portion 92; said proximal portion 92 is connected at its distal end 93 to an elongate, generally cylindrical distal portion 94. Said proximal portion 92 is also connected at its distal end 93 to a generally cylindrical intermediate portion 95 which is secured in transversely spaced relation to the elongate distal portion 94. Said cylindrical intermediate portion 95 constitutes a female engaging portion which is adapted to receive a generally cylindrical male engaging portion of a second elongate prosthesis (not shown). The male engaging portion is equipped with circumferentially spaced external barbs to engage in the female cooperating portion in service. As shown in Figure 7, the whole of the bifurcated prosthesis 91 is covered with an external fabric graft layer save for a flared portion 96 towards the proximal end 97 of the proximal portion 92.

[0080] Two embodiments of straight prothesis members are described herein, each comprising axially aligned stent segments, each of the segments comprising one or more adjacent hoops, perpendicular to a common axis, and each hoop being formed of wire in a sinuous or zigzag configuration with some or all of the juxtaposed apices in adjacent hoops secured to one another.

[0081] First, referring to Figure 8, a straight stent 400 comprises proximal stent portion (or segment) 401, distal stent portion 402, and an intermediate portion 403.

[0082] Proximal portion 401 is a ring formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above. In the illustrated embodiment, two hoops 20 are used, each hoop 20 having a unit width.

[0083] Distal portion 402 is also a ring formed of longitudinally displaced hoops 20 in the manner described above. Distal ring 402 has two hoops 20 of unit width in the illustrated embodiment.

[0084] Intermediate portion 403 of straight stent 400 is formed of biocompatible woven fabric such as, for example, a plain woven fabric made from 30 or 40 denier polyester. In this embodiment, intermediate fabric section 403 does not cover a stent. Fabric portion 403 is attached at its proximal and distal ends to the proximal and distal stent portions, respectively, by stitching, for example, with 0.003 inch polypropylene filaments around apices 22 of the stent portions. Other than such connections at its longitudinal ends, intermediate fabric section 403 is unsupported by any stent.

[0085] The second embodiment of a straight prothesis member that may be used in the invention is illustrated in Fig. 9. Straight stent 450 includes stent portion 451, constructed of wire loops as described above with reference to stent portions 401 and 402. Stent portion 451 is partially covered by fabric 452. In this embodiment, fabric portion 451 covers and is supported by stent 451, whereas with stent 400. the fabric portion 403 is not supported by a stent.

[0086] The angeological disease of occlusion is the blockage of an artery resulting from a buildup or clot of soft thrombus. There are two types of occlusions that can occur at the aorta-iliac bifurcation. The first is infrarenal occlusion. In this case, the blockage extends in the aorta from just below the renal arteries into the iliac arteries. The second type is an occlusion that is limited to the immediate area of the bifurcation.

[0087] To treat an infrarenal occlusion, a canalization is first made through the thrombus by methods known in the art. A bifurcated endoluminal prosthesis according to the present invention is then implanted at the bifurcation site to provide an unobstructed lumen extending from the aorta into each of the iliac arteries. Blood can thus flow freely from the aorta to the iliac arteries.

[0088] The bifurcated endoluminal prosthesis according to the present invention that is used to treat an occlusion must be fabric covered. This is necessary to prevent embolization from the thrombus remaining on the wall of the recanalized artery.

[0089] An occlusion at the bifurcation is treated by recanalizing the artery as above. A bifurcated endoluminal prosthesis according to the present invention may be implanted at the bifurcation. Because the occlusion is limited to the immediate bifurcation site, however, the proximal portion of the prosthesis may be shorter than that discussed above.

[0090] Using the apparatus of this invention to treat occlusion provides an unobstructed lumen through which blood can flow from the aorta to the iliac arteries.

[0091] The angeological disease of stenosis is a narrowing of an artery caused by a buildup of hard calcified plaque. This is usually caused by a buildup of cholesterol. To treat such an angeological disease, angioplasty is performed on the plaque according to methods well known in the art. The bifurcated endoluminal prothesis according to the present invention is then implanted at the bifurcation site. This prothesis is the same as that described above for treatment of an abdominal aortic aneurysm. To treat the stenosis, however, it is not necessary to cover the stent with a fabric, thus creating a prosthesis. Because restenosis is rare at the bifurcation site, there is no need to isolate the blood flowing in the lumen from the walls of the arteries.

Claims

1. A prosthesis for use at an angeological bifurcation of a blood vessel into two branched vessels, characterised by:

   a first prosthesis member (10;50;70;91) including a stent and adapted to be retained in said blood vessel, said first prosthesis member being bifurcated and including a proximal portion (12;52;72;92) adapted to be positioned in service in juxtaposition with the angeological bifurcation, and two distal portions (16,18;58,60; 78,80;94,95), one of which distal portions comprises a female co-operating portion adapted to engage a male engaging portion of another prosthesis member; and

   a second prosthesis member (40;86) also including a stent and including a male engaging portion by which said second prosthesis member is adapted to be joined in situ with said one distal portion of said first prosthesis member, said second prosthesis member being adapted to extend across the angeological bifurcation and into one of the branched vessels.

2. A prosthesis as claimed in claim 1, wherein each of said distal portions comprises a female co-operating portion adapted to engage a male engaging portion of another prosthesis member.

3. A prosthesis as claimed in claim 1 or 2, wherein one of said distal portions of said first prosthesis member is adapted to extend across the bifurcation into the other of said branched vessels.

4. A prosthesis as claimed in claim 1, wherein one of

said distal portions is adapted to be joined to said second prosthesis member, and the other distal portion is adapted to extend across the angeological bifurcation to allow blood flow into the other of the branched vessels.

5. A prosthesis as claimed in any preceding claim wherein at least one of said distal portions comprises a distal stent portion.

6. A prosthesis as claimed in claim 5, wherein said first bifurcated prosthesis member comprises a proximal stent portion.

7. A prosthesis as claimed in claim 6, wherein said proximal stent portion is formed integrally with said distal stent portion.

8. A prosthesis as claimed in claim 6, wherein said proximal stent portion is formed separately from said distal stent portion.

9. A prosthesis as claimed in any preceding claim wherein the stent of the first and/or second prosthesis members comprises sinuous wire formed into a tubular configuration comprising a plurality of hoops.

10. A prosthesis as claimed in claim 9, wherein said wire has an helical configuration.

11. A prosthesis as claimed in claim 9, wherein the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the tubular configuration.

12. A prosthesis as claimed in any of claims 9-11 wherein the wire is a shape memory nickel/titanium wire having a tubular configuration, and said stent has a diameter greater than the diameter of the blood vessel or branched vessel in which the prosthesis is intended to be used.

13. A prosthesis as claimed in claim 11 wherein the plane of the circumference of the hoop at each longitudinal end of the stent is square to the longitudinal axis of the stent.

14. A prosthesis as claimed in any of claims 9-13 further comprising securing means for securing adjacent hoops.

15. A prosthesis as claimed in claim 14 wherein said securing means comprise a loop element.

16. A prosthesis as claimed in any preceding claim wherein said male engaging portion (42;88) comprises a frustoconical wall which flares outwardly towards its longitudinal extremity.

17. A prosthesis as claimed in any preceding claim wherein said female cooperating portion comprises a frustoconical wall which tapers radially inwardly towards its longitudinal extremity.

18. A prosthesis as claimed in any preceding claim wherein said first bifurcated prosthesis member comprises a proximal end (54;82;96) that is flared radially outwardly towards its extremity to engage the endoluminal surface of the blood vessel, thereby to resist longitudinal movement of the first bifurcated prosthesis member in service.

19. A prosthesis as claimed in any preceding claim wherein each of said first and second prosthesis members comprises a graft layer.

20. A prosthesis as claimed in claim 19 wherein said graft layer is disposed internally of a stent.

21. A prosthesis as claimed in claim 19 wherein said graft layer is disposed externally of a stent.

22. A prosthesis as claimed in claim 19, claim 20 or claim 21 wherein said graft layer covers the entire length of a stent.

23. A prosthesis as claimed in any of claims 19-22 wherein said first bifurcated prosthesis member and/or said second prosthesis member includes a portion at which said graft layer is not supported by a stent.

24. A prosthesis as claimed in any of claims 19-23 wherein:

a first graft layer is disposed internally of at least one of said distal portions which is a female cooperating portion; and

a second graft layer is disposed externally of said second prothesis member.

25. A prosthesis as claimed in any of claims 19-23 wherein:

a first graft layer is disposed externally of said female cooperation portion and folds over the distal extremity of said female cooperating portion to form an inner sleeve; and

a second graft layer is disposed externally of said male engaging portion and contacts said inner sleeve to form a substantially blood-tight seal.

26. A prosthesis as claimed in any of claims 19-25 wherein said prosthesis includes a portion having a graft layer disposed internally and externally of a stent.

27. A prosthesis as claimed in any of claims 19-26 wherein the graft layer composes a bio-compatible fabric selected from the group consisting of polyester fabric and polytetrafluoroethylene fabric.

28. A prosthesis as claimed in any of claims 19-26 wherein the graft layer comprises a fabric selected from the group consisting of woven polyester fabric and a warp knitted polyester fabric.

29. A prosthesis as claimed in any preceding claim further comprising barbs to secure said prosthesis to said blood vessel.

Patentansprüche

1. Prothesen zur Verwendung in einer angiologischen Verzweigung eines Blutgefäßes in zwei verzweigte Blutgefäße, **gekennzeichnet durch** ein erstes Prothesenelement (10:50; 70:91) mit einem Stent, der dazu geeignet ist, in einem Blutgefäß zu verbleiben, dessen erstes Prothesenelement verzweigt ausgebildet ist und einen proximalen Bereich (12; 52:72; 92) aufweist, der dazu geeignet ist, im Einsatz in Juxta-Position mit der angiologischen Verzweigung angeordnet zu werden, und zwei distalen Bereichen (16, 18; 58, 60; 78, 80; 94, 95), wobei einer der distalen Bereiche einen aufnehmenden Anschlußbereich aufweist, der dazu geeignet ist, mit einem einzuführenden Eingreifendenbereich eines anderen Prothesenelements verbunden zu werden; und
einem zweiten Prothesenelement (40; 86), der ebenfalls einen Stent und einen einzuführenden Eingreifendenbereich aufweist, wobei das zweite Prothesenelement dazu geeignet ist, in situ mit dem ersten distalen Abschnitt des ersten Prothesenelementes verbunden zu werden, das zweite Prothesenelement dazu geeignet ist, sich über die angiologische Verzweigung in eines der verzweigten Gefäße zu erstrecken.

2. Prothese nach Anspruch 1, wobei jeder der distalen Bereiche einen aufnehmenden Anschlußbereich aufweist, der dazu geeignet ist, mit einem einzuführenden Eingreifendenbereich eines anderen Prothesenelementes verbunden zu werden.

3. Prothese nach Anspruch 1 oder 2, wobei einer der distalen Bereiche des ersten Prothesenelementes dazu geeignet ist, sich über die Verzweigung in das andere verzweigte Gefäß zu erstrecken.

4. Prothese nach Anspruch 1, wobei einer der distalen Bereiche dazu geeignet ist, mit dem zweiten Prothesenelement verbunden zu werden und der andere distale Bereich dazu geeignet ist, sich über die angiologische Verzweigung zu erstrecken, um dem Blutfluß zu erlauben, in das andere verzweigte Gefäß zu fließen.

5. Prothese nach einem der Ansprüche 1 bis 4, wobei zumindest einer der distalen Bereiche einen distalen Stentbereich umfaßt.

6. Prothese nach Anspruch 5, wobei das erste verzweigte Prothesenelement einen proximalen Stentbereich umfaßt.

7. Prothese nach Anspruch 6, wobei der proximale Stentbereich mit dem distalen Stentbereich integral ausgebildet ist.

8. Prothese nach Anspruch 6, wobei der proximale Stentbereich von dem distalen Stentbereich getrennt ausgebildet ist.

9. Prothese nach einem der Ansprüche 1 bis 8, wobei der Stent des ersten und/oder zweiten Prothesenelements sinusförmige Drähte umfaßt, die in einer röhrenförmigen Konfiguration ausgebildet sind und eine Vielzahl von Ringen umfaßt.

10. Prothese nach Anspruch 9, wobei der Draht eine schraubenlinienförmige Konfiguration aufweist.

11. Prothese nach Anspruch 9, wobei die Umfangsebene jedes Ringes im wesentlichen rechtwinkelig zu der Längsachse der röhrenförmigen Konfiguration ausgebildet ist.

12. Prothese nach einem der Ansprüche 9 bis 11, wobei der Draht aus Formgedächtnis (Nickel, Titan) Draht besteht, der eine röhrenförmige Konfiguration aufweist und der Stent einen Durchmesser hat, der größer ist als der Durchmesser des Blutgefäßes oder des verzweigten Gefäßes, in das die Prothese vorgesehen ist, verwendet zu werden.

13. Prothese nach Anspruch 11, wobei die Umfangsebene des Ringes an jedem länglichen Ende des Stents rechteckig ausgebildet ist zu der Längsachse des Stents.

14. Prothese nach einem der Ansprüche 9 bis 13, wobei Sicherungsmittel zum Sichern der benachbarten Ringen weiterhin vorgesehen sind.

15. Prothese nach Anspruch 14, wobei die Sicherungsmittel ein Schlingenelement umfaßt.

16. Prothese nach einem der Ansprüche 1 bis 15, wobei der einzuführende Eingreifendenbereich (42; 88) eine kegelstumpfförmige Wand umfaßt, die sich nach außen aufweitet in Richtung ihrer Längserstreckung.

17. Prothese nach einem der Ansprüche 1 bis 16, wobei der aufnehmende Anschlußbereich eine kegelstumpfförmige Wand umfaßt, die radial verjüngt nach innen ist in Richtung ihrer Längserstreckung.

18. Prothese nach einem der Ansprüche 1 bis 17, wobei das erste gegabelte Prothesenelement ein proximales Ende (54; 82; 96) umfaßt, das sich radial nach außen in Richtung seiner Längserstreckung aufweitet, um die endoluminale Oberfläche des Blutgefäßes aufzunehmen, wobei der Längsbewegung des ersten vergabelten Prothesenelementes im Einsatz Widerstand entgegengebracht wird.

19. Prothese nach einem der Ansprüche 1 bis 19, wobei jede des ersten und zweiten Prothesenelementes eine Implantationsschicht umfaßt.

20. Prothese nach Anspruch 19, wobei die Implantationsschicht im Inneren des Stents angeordnet ist.

21. Prothese nach Anspruch 19, wobei die Implantationsschicht äußerlich am Stent angeordnet ist.

22. Prothese nach Anspruch 19, 20, oder 21, wobei die Implantationsschicht die gesamte Länge des Stents bedeckt.

23. Prothese nach einem der Ansprüche 19 bis 22, wobei das erste gegabelte Prothesenelement und/oder das zweite Prothesenelement einen Bereich aufweist, an dem die Implantationsschicht nicht von dem Stent unterstützt wird.

24. Prothese nach einem der Ansprüche 19 bis 23, wobei eine erste Implantationsschicht im Inneren auf zumindest einem distalen Bereich angeordnet ist, der einen aufnehmenden Anschlußbereich darstellt; und eine zweite Implantationsschicht äußerlich an dem zweiten Prothesenelement angeordnet ist.

25. Prothese nach einem der Anspruche 19 bis 23, wobei die erste Implantationsschicht äußerlich auf dem aufnehmenden Anschlußbereich angeordnet ist und über die distale Erstreckung des aufnehmenden Anschlußbereichs umgefaltet reicht, um eine innere Hülse zu formen; und die zweite Implantationsschicht äußerlich auf dem einzuführenden Eingreifendenbereich angeordnet ist und mit der inneren Hülse in Kontakt steht, um eine im wesentlichen blutdichte Dichtung zu bilden.

26. Prothese nach einem der Ansprüche 19 bis 25, wobei die Prothese einen Bereich aufweist, der sowohl eine innere und äußere Implantationsschicht des Stents aufweist.

27. Prothese nach einem der Ansprüche 19 bis 26, wobei die Implantationsschicht aus biokompatiblen Material besteht, das aus einer Gruppe von Polyestermaterial und Polytetrafluorethylenmaterial ausgewählt ist.

28. Prothese nach einem der Ansprüche 19 bis 26, wobei die Implantationsschicht aus einem Material besteht, das aus einer Gruppe von gewobenem Polyestermaterial und einem kettengewirkten Polyestermaterial ausgewählt ist.

29. Prothese nach einem der Ansprüche 1 bis 28, weiter bestehend aus Haken, um die Prothese an ein Blutgefäß zu sichern.

Revendications

1. Prothèse destinée à être utilisée pour une bifurcation angiologique d'un vaisseau sanguin en deux vaisseaux dérivés, caractérisée par :

   un premier élément de prothèse (10;50;70;91) comprenant un élargisseur adapté pour être retenu dans ledit vaisseau sanguin, ledit premier élément de prothèse étant bifurqué et comportant une partie proximale (12;52;72;92) apte à être positionnée en service d'une manière juxtaposée avec la bifurcation angiologique des deux parties distales (16,18;58,60;78,80; 94,95), l'une de ces parties distales comprenant une partie femelle coopérante apte à engrener avec une partie mâle d'engrènement d'un autre élément de prothèse; et
   un second élément de prothèse (40;86) comportant également un élargisseur et incluant une partie d'engrènement mâle, au moyen de laquelle ledit second élément de prothèse est adapté pour être réuni in situ à ladite première partie distale dudit premier élément de prothèse, ledit second élément de prothèse étant adapté pour s'étendre en travers de la bifurcation angiologique et dans l'un des vaisseaux dérivés.

2. Prothèse selon la revendication 1, dans laquelle chacune desdites parties distales comprenant une partie femelle coopérante adaptée pour engrener avec une partie d'engrènement mâle d'un autre élément de prothèse.

3. Prothèse selon la revendication 1 ou 2, dans laquel-

le l'une desdites parties distales dudit premier élément de prothèse est adaptée pour s'étendre en travers de la bifurcation dans l'autre desdits vaisseaux dérivés.

4. Prothèse selon la revendication 1, dans laquelle l'une desdites parties distales est adaptée pour être réunie audit élément de prothèse et l'autre partie distale est adaptée pour s'étendre en travers de la bifurcation angiologique de la manière à permettre une circulation du sang dans l'autre des vaisseaux dérivés.

5. Prothèse selon l'une quelconque des revendications précédentes, dans laquelle au moins l'une desdites parties distales comprend une partie distale formant élargisseur.

6. Prothèse selon la revendication 5, dans laquelle ledit élément de prothèse bifurqué comprend une partie proximale formant élargisseur.

7. Prothèse selon la revendication 6, dans laquelle ladite partie proximale formant élargisseur est formée d'un seul tenant avec ladite partie distale formant élargisseur.

8. Prothèse selon la revendication 6, dans laquelle la partie proximale formant élargisseur est formée séparément de ladite partie distale formant élargisseur.

9. Prothèse selon l'une quelconque des revendications précédentes, dans laquelle l'élargisseur du premier et/ou du second éléments de prothèse comprend un fil sinueux disposé sur une configuration tubulaire comprenant plusieurs cercles.

10. Prothèse selon la revendication 9, dans laquelle ledit fil possède une configuration hélicoïdale.

11. Prothèse selon la revendication 9, dans laquelle le plan de la circonférence de chaque cercle est sensiblement perpendiculaire à l'axe longitudinal de la configuration tubulaire.

12. Prothèse selon l'une quelconque des revendications 9-11, dans laquelle le fil est un fil de nickel/titane à mémoire de forme ayant une configuration tubulaire, et ledit élargisseur possède un diamètre supérieur au diamètre du vaisseau sanguin ou du vaisseau dérivé, dans lequel la prothèse doit être utilisée.

13. Prothèse selon la revendication 11, dans laquelle le plan de la circonférence du cercle à chaque extrémité longitudinale de l'élargisseur est perpendiculaire à l'axe longitudinal de l'élargisseur.

14. Prothèse selon l'une quelconque des revendications 9-13, comprenant en outre des moyens de fixation pour fixer les cercles adjacents.

15. Prothèse selon la revendication 14, dans laquelle lesdits moyens de fixation comprennent un élément formant boucle.

16. Prothèse selon l'une quelconque des revendications précédentes, dans laquelle ladite partie d'engrènement mâle (42;88) comprend une paroi tronconique, qui s'évase vers l'extérieur en direction de son extrémité longitudinale.

17. Prothèse selon l'une quelconque des revendications précédentes, dans laquelle ladite partie femelle coopérante comprend une paroi tronconique qui se rétrécit radialement vers l'intérieur en direction de son extrémité longitudinale.

18. Prothèse selon l'une quelconque des revendications précédentes, dans laquelle ledit premier élément de prothèse bifurqué comprend une extrémité proximale (54;82;96) qui est évasée radialement vers l'extérieur en direction de son extrémité pour s'appliquer contre la partie endoluminale du vaisseau sanguin, de manière à résister ainsi à un déplacement longitudinal du premier élément de prothèse bifurqué, en cours d'utilisation.

19. Prothèse selon l'une quelconque des revendications précédentes, dans laquelle chacun desdits premier et second éléments de la prothèse comprend une couche formant greffe.

20. Prothèse selon la revendication 19, dans laquelle ladite couche formant greffe est disposée à l'intérieur d'un élargisseur.

21. Prothèse selon la revendication 19, dans laquelle ladite couche formant greffe est disposée à l'extérieur d'un élargisseur.

22. Prothèse selon la revendication 19, la revendication 20 ou la revendication 21, dans laquelle ladite couche formant greffe recouvre l'élargisseur sur toute sa longueur.

23. Prothèse selon l'une quelconque des revendications 19-22, dans laquelle ledit premier élément de prothèse bifurqué et/ou ledit second élément de prothèse comprennent une partie dans laquelle ladite couche formant greffe n'est pas supportée par un élargisseur.

24. Prothèse selon l'une quelconque des revendications 19-23, dans laquelle :

la première couche formant greffe est disposée à l'intérieur d'au moins l'une desdites parties distales, qui est une partie femelle coopérante; et
la seconde couche formant greffe est disposée à l'extérieur dudit second élément de prothèse.

25. Prothèse selon l'une quelconque des revendications 19-23, dans laquelle :

une première couche formant greffe est disposée à l'extérieur de ladite partie femelle coopérante et est repliée par dessus l'extrémité distale de ladite partie femelle coopérante pour former un manchon intérieur; et
une seconde couche formant greffe est disposée à l'extérieur de ladite partie d'engrènement mâle et est en contact avec ledit manchon intérieur pour former un joint d'étanchéité essentiellement étanche au sang.

26. Prothèse selon l'une quelconque des revendications 19-25, dans laquelle ladite prothèse comprend une partie possédant une couche formant greffe disposée sur le côté intérieur et sur le côté extérieur d'un élargisseur.

27. Prothèse selon l'une quelconque des revendications 19-26, dans laquelle la couche formant greffe comprend un tissu biocompatible choisi dans le groupe comprenant un tissu de polyester et un tissu de polytétrafluoroéthylène.

28. Prothèse selon l'une quelconque des revendications 19-26, dans laquelle la couche formant greffe comprend un tissu choisi dans le groupe comprenant un tissu de polyester tissé et un tissu de polyester tricoté en chaîne.

29. Prothèse selon l'une quelconque des revendications précédentes, comprenant en outre des barbes pour fixer ladite prothèse audit vaisseau sanguin.

FIG. 1A

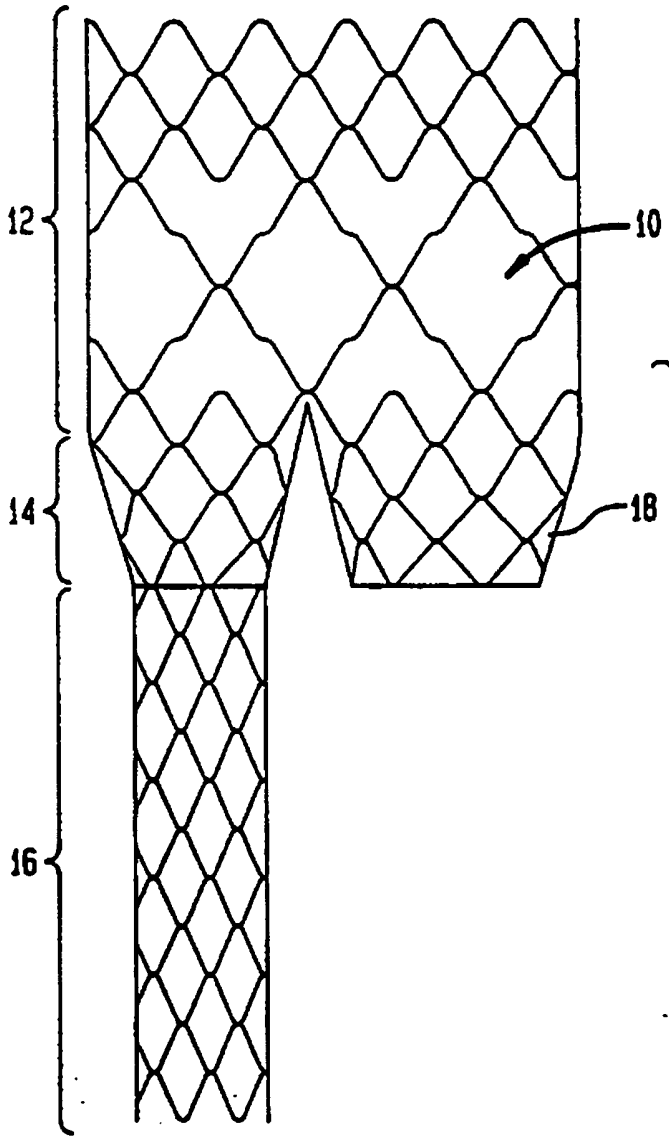

FIG. 1B

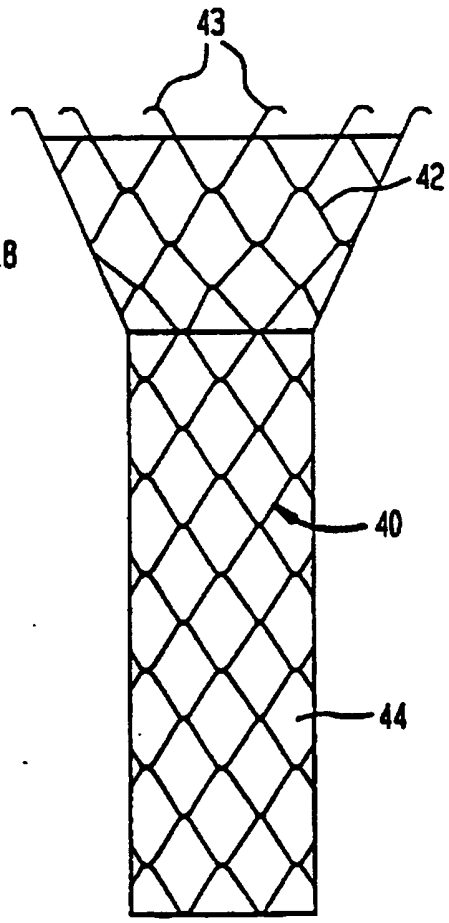

FIG. 2A

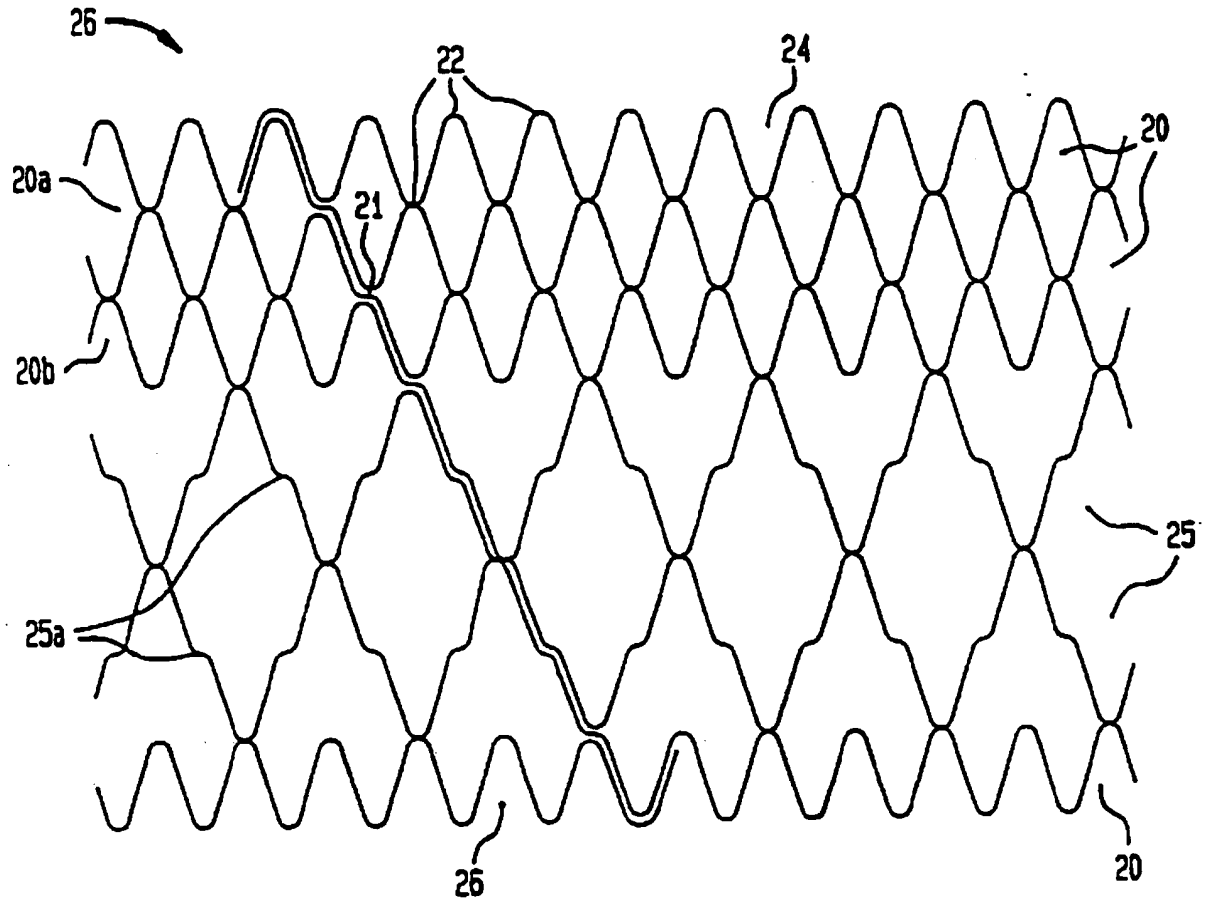

FIG. 2B

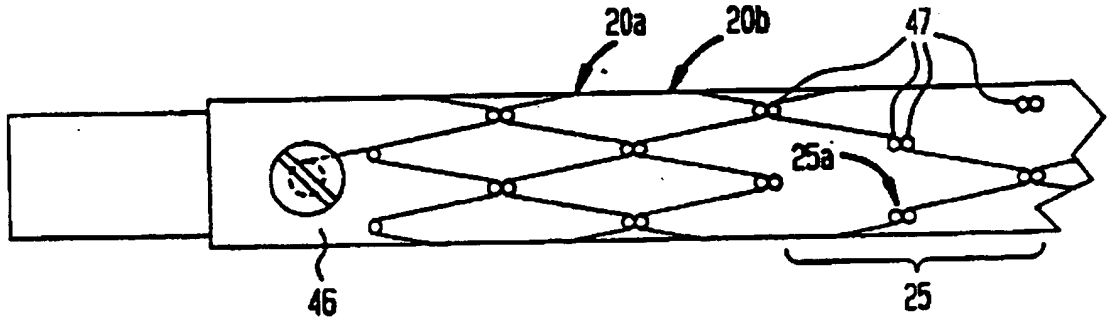

FIG. 3

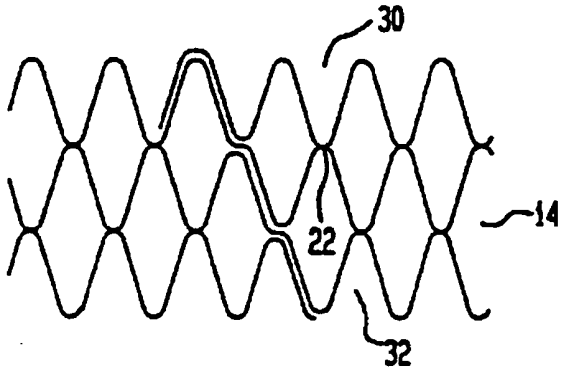

FIG. 4A

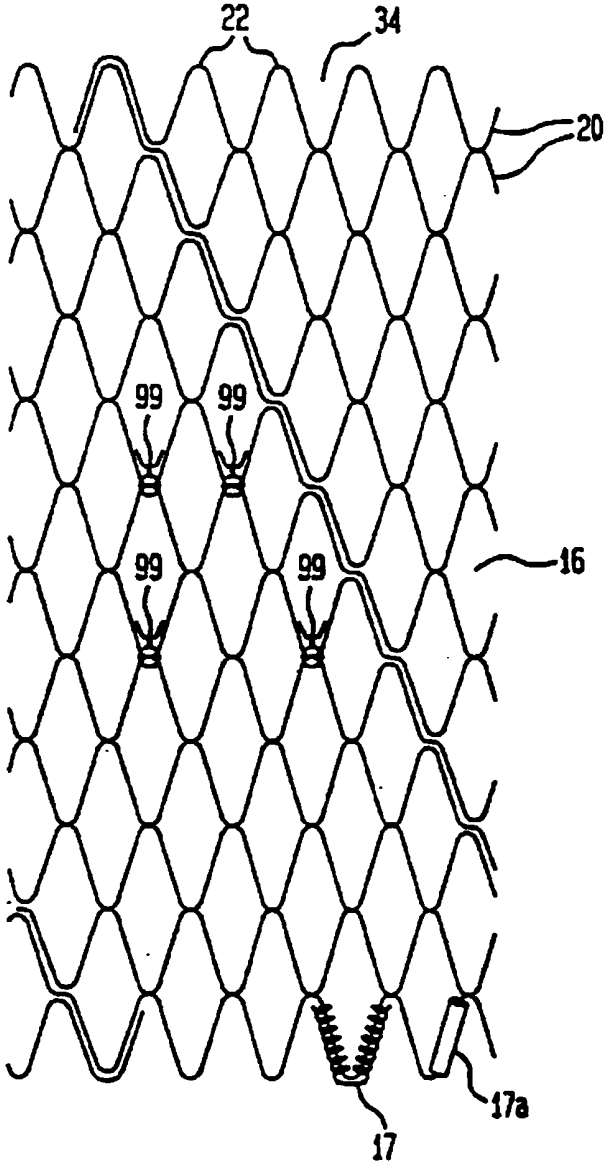

FIG. 4B

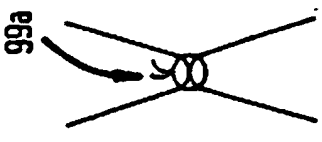

FIG. 4C

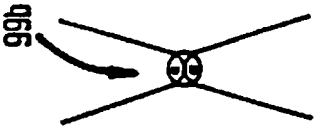

FIG. 4D

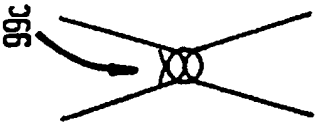

FIG. 4E

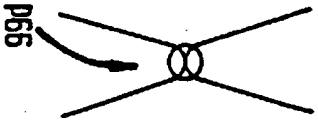

FIG. 4F

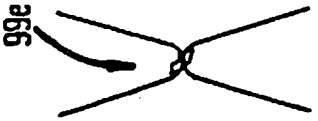

FIG. 5

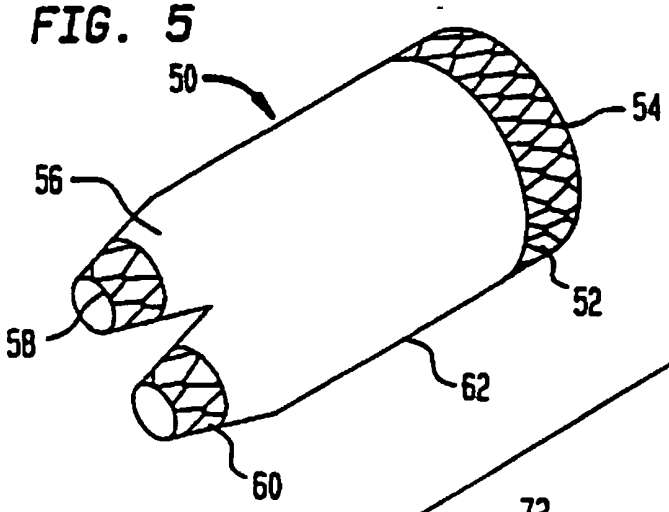

FIG. 6

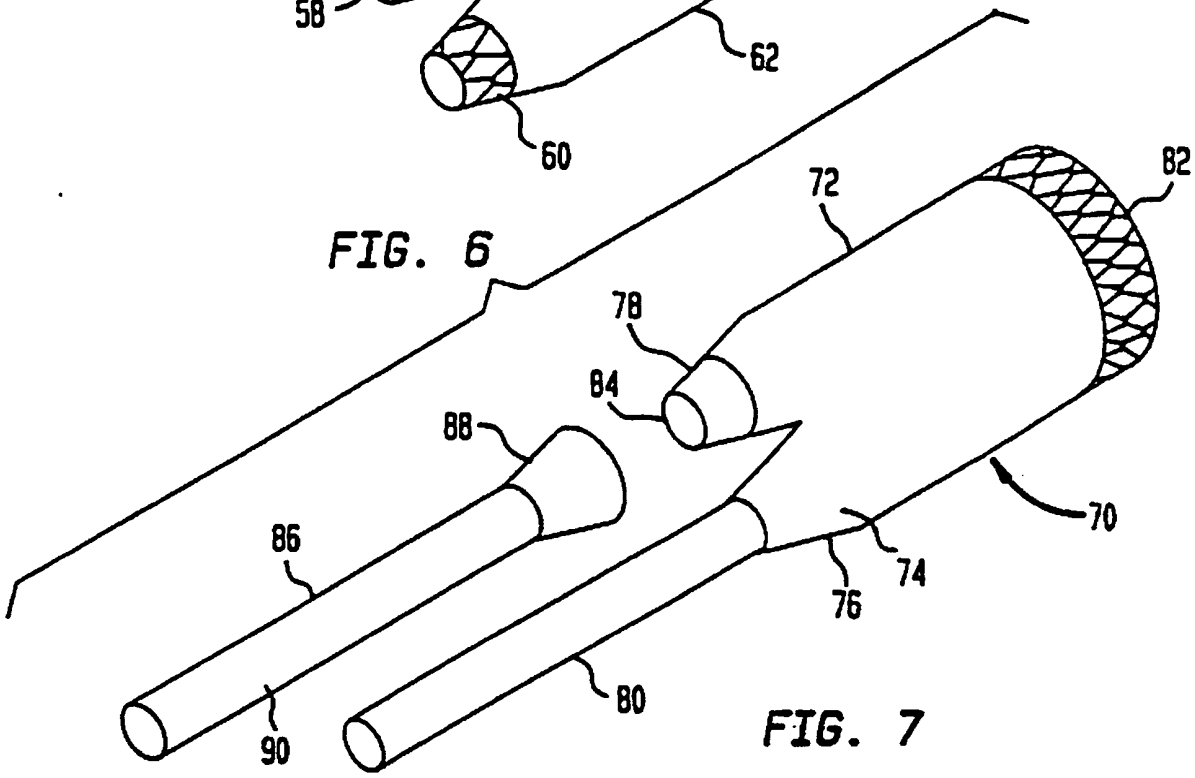

FIG. 7

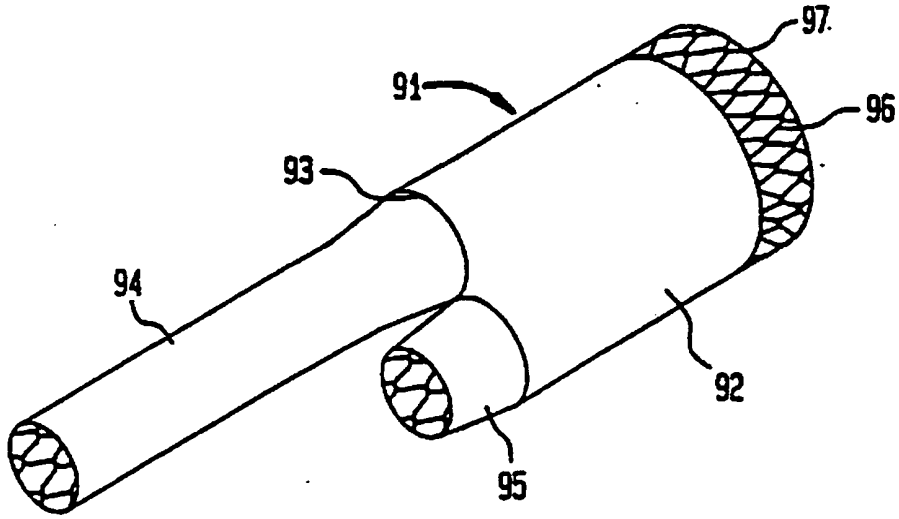

FIG. 9

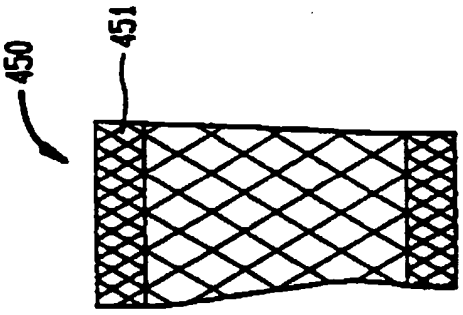

FIG. 8